UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re:

DOW CORNING CORPORATION,

Reorganized Debtor.

Civil Action No. 05-CV-30533-DT
Honorable Denise Page Hood

Ewell Wood, on behalf of decedent Denise Wood,

v.

DCC Litigation Facility Incorporated.

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MEMORANDUM OPINION AND ORDER

I. BACKGROUND/FACTS[1]

Claimant Ewell Wood, on behalf of the Estate of Denise Wood, opted out of the settlement process before the Settlement Facility-Dow Corning Trust ("SF-DCT") as provided under the Dow Corning Amended Joint Plan of Reorganization ("Plan"). The Effective Date for the confirmed Plan was June 1, 2004. (April 2, 2004 Order Establishing Effective Date, Bankruptcy Case No. 95-20512) Pursuant to the Plan, claimants who choose to litigate must file claims against the DCC Litigation Facility ("Litigation Facility"). (Plan, Art. 5.4, 6.1)

Decedent Ms. Wood is a Class 8 medical device recipient, a Becker Expander/Mammary Prosthesis ("Becker Expander") manufactured by Mentor Corporation[2] ("Mentor"). (LF Ex. A,

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[1] The following published opinions provide a detailed history of this bankruptcy action: *In re Dow Corning Corp.*, 255 B.R. 445 (E.D. Mich. 2000), 86 F.3d 482 (6th Cir. 1996), 113 F.3d 565 (6th Cir. 1997), 280 F.3d 648 (6th Cir. 2002), and 456 F.3d 668 (6th Cir. 2006).

[2] In 1984, Mentor purchased Heyer-Schulte.

3/4/05 Questionnaire, p. 13) The Becker Expander consisted of a saline-filled shell inside a gel-filled outer shell. Saline could be added to the inner shell after surgery to promote tissue growth or expansion and to adjust size without additional procedures. The tube used to add the saline was removed after the reaching the desired expansion and the device was converted to a permanent mammary implant. (LF Br., p. 4., n. 2) Ms. Wood was implanted with the Becker Expander on October 2, 1987. (LF Ex. A, 3/4/05, p. 13; LF Ex. D, Operation Record 10/2/87) The Becker Expander was removed and reported as ruptured on April 24, 1991. (LF Ex. A, 3/4/05 Questionnaire, p. 5, LF Ex. E, Operation Record 4/24/91)

The Litigation Facility moves for summary judgment on the Class 8 medical device claim submitted by Claimant. The Litigation Facility raises two arguments in support of its motion. The first is that the Claimants' claims are barred by the bulk supplier and sophisticated purchaser defense because Mentor altered and incorporated those materials into its own unique implant designs. The second argument is that the claims are barred because the Becker Expander ruptured, a condition for which Dow Corning, as the raw material supplier, cannot be held liable since such claims can only be asserted against the manufacturer. The Litigation Facility claims Dow Corning played no role in the design, manufacture or marketing of the finished implants. The Litigation Facility reserves its right to later challenge Claimant's claim based on product identification, which is not addressed in this motion.

No response was filed by Claimant to the Litigation Facility's Motion for Summary Judgment. The Plaintiffs' Liaison Counsel ("Liaison Counsel") submitted a response arguing in opposition that there is a genuine issue of material fact as to whether the commercial gel kits Dow Corning sold to other implant manufacturers were defective due to Dow Corning's superior

knowledge of the bio-reactivity of the silicones in its gel, resulting in Dow Corning's failure to adequately warn purchasers of the known hazards. The Liaison Counsel also argues that summary judgment is inappropriate on the Class 8 claim arising from the rupture of implants made by Mentor because it was reasonably foreseeable to Dow Corning that implants made by Mentor would rupture, resulting in injuries caused by the exposure to the silicone gel provided by Dow Corning.

Dow Corning admittedly began supplying silicone raw materials to other breast implant manufacturers, including two types of silicone precursors that Dow Corning supplied to Heyer-Schulte/Mentor. One type of material is referred to as "Gel Raw Materials" consisting of precursor silicone fluids that could be processed to make silicone gel. Dow Corning claims the manufacturer determined the combinations of Gel Raw Materials, formulated and mixed them, processed them at the manufacturer-specified temperature for a specified time, and marketed these implants. (LF Br. in 05-30551, pp. 5-6)[3]

The second type of silicone raw material provided by Dow Corning was a precursor of silicone elastomer (a rubbery solid) solid in the form of either viscous "slurry" or a gum, referred to as "Elastomer Raw Materials." The manufacturer would mill the gum, mix it with a solvent, and stir the mixture using a propeller-type mixing machine until it formed a silicone "dispersion" or "slurry." The manufacturer would form the envelope by dipping a mandrel shaped like breast implant into the viscous dispersion, increasing the number of dips, depending on what the manufacturers' specifications were as to the thickness of the envelope. The coated mandrel would

[3] The Litigation Facility incorporates the facts set forth in Section III of its Memorandum of Law in Support of its Motion for Summary Judgment of Class 7 Raw Material Supplier Claims filed in Case No. 05-30551, Doc. No. 3. The citations in this Opinion refers to the Litigation Facility's briefs and documents filed in Case No. 05-30551.

then be heated to form a solid, finished silicone elastomer for the implant's outer envelope. (LF Br. in 05-30551, pp. 6-7)

The materials were provided by Dow Corning to the purchasers and manufacturers of these materials with a statement that Dow Corning was not responsible for the end-product since Dow Corning could not test and determine the suitability and safety of these materials for use in the purchaser's intended applications. (Ex. B to LF's Br. in 05-30551, ¶ 19)

Heyer-Schulte was founded by individuals with experience in medical devices, including silicone materials, initially using silicone rubber to improve hydrocephalus shunts. Heyer-Schulte began manufacturing silicone breast implants in 1969 or 1970 (Ex. B to LF's Br. in 05-30551, ¶¶ 11, 13, 18) In 1974, Heyer-Schulte was acquired by American Hospital Supply Company ("AHS"), a supplier and manufacturer of medical products. Mentor Corporation purchased AHS's plastic surgery business assets, including Heyer-Schulte in 1984. Heyer-Schulte went to Dow Corning to supply some of its silicone gel raw materials after General Electric withdrew from supplying silicone materials. (Ex. B to LF's Br. in 05-30551, ¶¶ 35-36) Heyer-Schulte used its own composition of the Dow Corning Gel Raw Materials describing the gel as "Dow Corning gel formulation as manufactured here at Heyer-Schulte." (Ex. B to LF's Br. in 05-30551, ¶ 37) Heyer-Schulte principals testified that Heyer-Schulte conducted its own safety testing on both the purchased raw materials and the finished breast-implant products. (Ex. B to LF's Br. in 05-30551, ¶¶ 39, 46-47)

In 1976, both Heyer-Schulte began purchasing silicone gel from Dow Corning as a two-part "gel kit." (Condra Aff. I, Ex. 2, ¶¶ 7, 8) The product information bulletin described the gel kit as the "Dow Corning Q7-2167/Q7-2168 Silicone Gel System," a "two-part system designed for producing a responsive silicone gel." (Condra Aff. I, Ex. 19) Nothing was added to the two-part

system by Heyer-Schulte. (Condra Aff. I, Ex. 18, ¶ 10) Dow Corning's recommendation was to mix three (3) parts of Q7-2167 and one (1) part Q7-2168, cook it at 320°F for three hours and twenty minutes to obtain a gel with "optimum properties." (Condra Aff. I, Ex. 19) Dow Corning used the same ratio, time and temperature in its own silicone gel breast implants. (Condra Aff. I, Ex. 20) Heyer-Schulte generally followed Dow Corning's recommendations for the gel. (Condra Aff. I, Exs. 21-24) The manufacturing operation did not chemically alter the silicone, and the finished gel contained 80-90% liquid silicone. (Condra Aff. I, Exs. 25-26)

The chemical details of Dow Corning's gel was not shared with Heyer-Schulte, other than describing the gel as a "polydimethylsiloxane composition." (Condra Aff. I, Ex. 11) Dow Corning knew that Heyer-Schulte was using Dow Corning's gel kits to make silicone gel breast implants. (Condra Aff. I, Ex. 28) The brochure distributed by Dow Corning represented that Dow Corning was the leading authority on the medical/silicone subject, that the silicone materials were tested more thoroughly by Dow Corning than others, that no one could match Dow Corning's years of controlled studies history on the implantation of silicones and, by purchasing silicone products such as gel from Dow Corning, manufacturers could reduce the need for time consuming inspection and testing, indicating that "We've already done it for you." (Condra Aff. I, Ex. 11) The brochure further states "Quality" is "the comforting knowledge that Dow Corning silicones will meet the requirements you would specify if the device were used in your own body." (Condra Aff. I, Ex. 11) "Also, in a litigious society, the quality of raw materials, and the confidence that the company supplying them will stand behind them, are value-added benefits worth your consideration." (Condra Aff. I, Ex. 32) Dow Corning encouraged its customers not to conduct their own testing on Dow Corning's "medical grade" silicone gel, but rather to rely on the safety testing already

performed by Dow Corning. (Condra Aff. I, Ex. 12) Heyer-Schulte was under the impression that Dow Corning had valid data to support the long-term safety of its silicone gel. (Condra Aff. I, Exs. 12, 31)

In a September 23, 1983 memorandum, a Dow Corning scientist indicated that the gel being supplied to the other manufacturers (Q7-2167/2168) had never been specifically tested for long-term safety and that Dow Corning had no such data. (Condra Aff. I, Ex. 32) The scientist expressed concern that Dow Corning was misrepresenting to its silicone gel customers that the "safety testing to qualify [silicone gels] as implant materials does exist and can obtained readily from Dow Corning." (Condra Aff. I, Ex. 33) Other than very limited short-term testing on Dow Corning's silicone gel, Heyer-Schulte conducted no further testing, acknowledging that it relied heavily on Dow Corning for the safety and biocompatibility of the silicone gel used in their breast implants. (Condra Aff. I, Exs. 34-35) A Dow Corning scientist proposed that an in depth study of Dow Corning's gel, envelope and bleed phenomenon was further required and that capsule contracture was not the only problem. (Condra Aff. I, Ex. 36)

In 1965, Dow Corning received permission from the Food and Drug Administration ("FDA") to begin clinical trials for the injection of silicone fluid for various cosmetic uses under an Investigational New Drug ("IND") Application. The FDA notified Dow Corning that its IND request did not contain sufficient data to support a conclusion that it was "reasonably safe" to continue clinical investigation. Dow Corning supplied additional data but the FDA again notified Dow Corning that its submission was inadequate. The IND was terminated in 1976. (Condra Aff. I, Ex. 38) Investigators discovered that the fluid, even when injected under the controlled conditions of a study, could trigger a chronic inflammatory response and edema with swelling and that the fluid

could migrate and accumulate and not be totally removed by surgery. (Condra Aff. I, Exs. 41-42)

The silicone gel used in breast implants are up to 90% liquid silicone fluid contained within a matrix of cross-linked polymers. (Condra Aff. I, Ex. 56) It is generally referred to as polydimethylsiloxane but the fluid contained thousands of different polydimethylsiloxanes, including low molecular weight cyclics D_4, D_5, D_6, D_7 and linear versions of the cyclic polymers. The silicone elastomer shell is more cross-linked and contains a larger percentage of higher molecular weight components, with up to 30% of the shell consisting of silica (SiO_2).

Dow Corning discovered extreme biological activity in a silicone compound called 2,6-cis, a compound related to D_4 except that it contains a phenyl component. Dow Corning thereafter intended to develop commercial products exploiting the biologic activity of the whole range of silicone compounds. Dow Corning's Bioscience Research Department found various silicones, including some of the polydimethylsiloxanes used in its silicone gel, to have unexpected effects suggesting biological activity and mobility in the human body. (Condra Aff. I, Ex. 46). By the early 1970's, Dow Corning was focusing on the effectiveness of various polydimethylsiloxanes, including D_4, as adjuvants, which is a substance that causes the body's immune system to attack itself. (Condra Aff. I, Ex. 49) Researches concluded in 1974 that the data indicated that organosilicon compounds can stimulate the immune response. (Condra Aff. I, Ex. 51) By January 1975, researchers found that various organosilicon fluids, including polydimethylsiloxane fluids contained in breast implants potentiated the formation of humoral antibody, modulated cell mediated immunity and promoted the induction of interferon by stimulation of the immune system. (Condra Aff. I, Ex. 53) Later testing revealed that some of the polydimethylsiloxanes in breast implants also produced eosinophilia, which is considered indicative of an allergic response and that low molecular weight

silicones impaired the phagocytic ability of macrophages. (Condra Aff. I, Ex. 53) The macrophages, the cells that engulf foreign substances in the body, were impaired in their ability to secrete the foreign substances from the body. (Condra Aff. I, Ex. 54) Dow Corning did not disclose these results to Heyer-Schulte when Dow Corning began supplying its silicone gel to Heyer-Schulte in 1976. Dr. Donald Bennett of Dow Corning, recommended to executives in 1974 the establishment of a patient registry for breast implants because of the concern about silicone's local and systemic biological activity and its ability to migrate in the body. (Condra Aff. I, Ex. 46)

In 1972, Dow Corning began a long-term clinical study, conducted during the years it sold silicone gel kits, among fifty women with silicone breast implants, following the women for ten years. The results were never published or disclosed to Heyer-Schulte or to the FDA. (Condra Aff. I, Ex. 55) The results revealed that nine out of forty-two women followed developed problems with pain and/or inflammation. (Condra Aff. I, Ex. 55)

Various other studies were performed in the 1970's and 1980's by Dow Corning. Some studies found depolymerization, the conversion of high molecular weight polydimethylsiloxanes to potentially more dangerous low molecular weight polydimethylsiloxanes, metabolism to silanols through a hydrolysis reaction. (Condra Aff. I, Exs. 64-66) In 1985, Dow Corning conducted a follow-up thirty-day test to investigate the possibility of immunological sensitization to a component of the gel formulation and found increased numbers of eosinophils were evident at the gel implant site, indicative of an allergic response. (Condra Aff. I, Ex. 69) This study was not published or disclosed to Dow Corning's silicone gel customers.

Another extensive program study was performed in 1985 to study the effects of the components of silicone gel breast implants in the immune system. Dow Corning scientists conceded

that the animal studies suggest that silicone materials may be able to modify the immune system. (Condra Aff. I, Ex. 71) This information was not conveyed to its silicone gel customers.

Dow Corning conducted a comprehensive review of all internally conducted safety studies of silicone gel implants in late 1986 and noted that silicone gel contained within a silicone elastomer shell induces a chronic inflammatory reaction with the same characteristics as noted for free gel. Resolution is never entirely achieved because the permeation of fluid through the shell is very slow and constitutes a rate-limiting process, that is, the contained gel functions as an infinite sink. (Condra Aff. I, Ex. 72) Dow Corning acknowledged that the gel from an implant was not contained within the fibrous capsule and that released polydimethylsiloxane would phagocytized at least in part by macrophages and giant cells. The phagocytic cells transport engulfed silicone to at least regional lymph nodes. (Condra Aff. I, Ex. 72) Dow Corning scientists postulated that phagocytized silicone will accumulate in draining lymph nodes, followed by slow transport to the liver, and will cycle to other tissues of the reticuloendothelial system. Elimination is assumed to occur at a slow rate via the lung alveolar phagocyte migration up the respiratory tree to the esophagus. (Condra Aff. I, Ex. 92)

Dow Corning summarized the deficiencies in the safety studies performed up to 1986, noting that the histopathology of the reticuloendothelial system has not been adequately assessed in any long-term study including determination of the organ distribution of silicone materials and that none of the existing studies critically assess possible systemic effects arising from the local inflammatory reaction or from material transport. These issues are relevant to the claims and suspicions of autoimmune-like disorders linked to silicone fluid and gel and to synovitis and lymphadenopathy associated with elastomer abrasion particles. (Condra Aff. I, Ex. 92) The report was not disclosed

to Dow Corning's silicone gel customers.

The Liaison Counsel claims that during the 1980s, Mentor's chief engineer, Bobby Purkait, made unsuccessful telephone inquiries in order to gain access to Dow Corning's long-term studies on its gel which was sold to Mentor. (Condra Aff. II, Ex. 2) Mentor and Dow Corning scientists met in Midland, Michigan in December 1988. Mentor was shown some test results from one two-year bioassay of the Q7-2167/2168 gel, a summary of the contents of the master Device File for the gel, and some short-term test results. (Condra Aff. II, Exs. 2, 4; Condra Aff., I, Ex. 13) Dow Corning did not show its long-term test results but assured Mentor that the long-term testing disclosed nothing that questioned the safety of the gel. (Condra Aff. II, Ex. 2) Dow Corning and Mentor representatives met again in Las Vegas, Nevada in 1990 at which time Dow Corning told Mentor that it did not have any tests which showed an immunological reaction with silicone. (Condra Aff. II, Ex. 2)

The Litigation Facility submitted with its reply brief various reports and documents to support its motion. The first report is the Rule 706 Science Panel Report which was ordered in the MDL-926 Breast Implant Litigation in 1996. The November 1998 Report by the Panel concluded that "[t]here was no association between silicone gel-filled implants and any of the definite connective tissue diseases (including Sjogren's Syndrome) or other autoimmune theumatic conditions." (LF's Reply Br., Ex. A) The Panel also found no association between atypical connective tissue diseases or any distinctive constellation of symptoms observed in women with breast implants. (*Id.)* The second report is the 1999 Institute of Medicine Report which found no convincing evidence to support clinically significant immunologic effects of silicone or silicone breast implants. (LF's Reply Br., Ex. B) The third report is the 1998 Britain Independent Review

Group Report which concluded that there was no hisopathological or conclusive immunological evidence for an abnormal immune response to silicone from breast implants in tissue nor any epidemiological evidence for any link between silicone gel breast implants and any established connective tissue disease. (LF's Reply Br., Ex. C) The fourth document is the FDA Summary of Safety & Effectiveness Data, Silicone Gel-Filled Breast Implants (Notice of Approval to Mentor re Mentor Memory Gel Silicone Gel-Filled Breast Implants PMA No. P030053) (Nov. 17, 2006) which approved the commercial sale of silicone-gel-filled implants after the FDA considered various reports, finding that "no cause and effect relationship has been established between breast implants and these conditions." (LF's Reply Br., Ex. D)

II. ANALYSIS

A. Summary Judgment Standard of Review

Rule 56(c) provides that summary judgment should be entered only where "the pleadings, depositions, answers to the interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The presence of factual disputes will preclude granting of summary judgment only if the disputes are genuine and concern material facts. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is "genuine" only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* Although the Court must view the motion in the light most favorable to the nonmoving party, where "the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986).

Summary judgment must be entered against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. *Celotex Corp.*, 477 U.S. at 322-23. A court must look to the substantive law to identify which facts are material. *Anderson*, 477 U.S. at 248.

B. Applicable Law

The Litigation Facility argues that the Court apply the sophisticated purchaser/bulk supplier doctrine but the Liaison Counsel responds by directing the Court to the test articulated in the Restatement (Third) of Torts: Products Liability (1998). The Litigation Facility claims that the Restatement is merely a restatement of the law on a particular subject. Whether referenced as the "bulk supplier," "raw material supplier," or "sophisticated purchaser" doctrine, the Litigation Facility argues that courts have universally adopted the core components of the doctrine, which are also articulated in the Restatement (Third) of Torts: Products Liability § 5 (2007). The Litigation Facility claims that there is essentially no conflict between the Third Restatement and the four-factor test articulated by the Honorable Sam Pointer in *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 996 F.Supp. 1110 (N.D. Ala. 1997). The Litigation Facility points to Judge Pointer's opinion which cites section 5 of the then-proposed final draft of the Restatement as recognizing and restating the defense as it exists in the case law. 996 F.Supp. at 1114.

The Supreme Court has discussed "the settled principle that '[c]reditors' entitlements in bankruptcy rise in the first instance from the underlying substantive law creating the debtor's obligation, subject to any qualifying or contrary provisions of the Bankruptcy Code.' That principle

requires bankruptcy courts to consult state law in determining the validity of most claims." *Travelers Casualty & Surety Co. of America v. Pacific Gas & Electric Co.*, 127 S.Ct. 1199, 1204-05 (2007) (citations omitted). Courts have long recognized that the basic federal rule in bankruptcy is that state law governs the substance of claims, Congress having generally left the determination of property rights in the assets of a bankrupt's estate to state law. *Id.* at 1205. When considering questions of state law, a federal court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation. *See TMJ Implants Prod. Liab. Lit. v. E.I. Du Pont De Nemours and Co.*, 97 F.3d 1050, 1055 (8th Cir. 1996). Products liability claims are state law actions. *Id.*

As noted by Judge Pointer in his opinion, the raw material/bulk supplier doctrine has been expressly adopted by a large number of jurisdictions. *In re Silicone Gel Breast Implant Lit.*, 996 F.Supp at 1113. The doctrine has been applied in Alabama, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Kansas, Louisiana, Michigan, Minnesota, Missouri, New Jersey, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. *Id.* For the purposes of this motion, the Court finds that there is essentially no difference between the Restatement elements as to the raw materials/bulk supplier doctrine and the test set forth in Judge Pointer's opinion, especially since Judge Pointer cited the Restatement in his opinion.

The Court notes that since there have been no Complaints filed in any of these cases, the Court is not ruling on the merits of any of this Class 8 Claimant's potential claims against the Litigation Facility. The Court will only address the defense raised by the Litigation Facility.

B. The Bulk Supplier/Raw Material Supplier/Sophisticated Purchaser Defense

1. Four-Factor Test

This Court applies the four-factor test noted by Judge Pointer to establish a sophisticated purchaser/raw material and bulk supplier defense: 1) whether the materials supplied in bulk were not themselves inherently dangerous; 2) whether the manufacturers who purchased the materials were sophisticated buyers; 3) whether the raw materials underwent substantial changes in the process of the manufacturer's incorporation of them into the finished end-product; and 4) whether the supplier substantially participated in design of the component into the design of the product. *Id.* at 1114-17.

2. Inherently Defective or Dangerous

The Litigation Facility argues[4] that a supplier of raw materials is not legally responsible for ensuring that its materials are incorporated into a product that is safe for all conceivable uses. The Litigation Facility claims that there is no evidence that the silicone materials supplied by Dow Corning to Heyer-Schulte/Mentor are inherently dangerous or defective. The Litigation Facility cites the report of the National Science Panel which found no association between the silicone gel-filled implants and disease or any distinctive constellation of symptoms. (National Science Panel Report at 4-5) The Litigation Facility argues that Judge Pointer found that the silicone supplied by General Electric was not inherently defective or unreasonably dangerous. *In re Silicone Gel Breast Implants*, 996 F.Supp. at 1114. The Litigation Facility claims that the Dow Corning silicone at issue was essentially identical to the General Electric silicone material. (Ex. B to LF's Br. in 05-30551,

[4] The Litigation Facility incorporates its arguments set forth in Section IV.A. of its Memorandum of Law in Support of its Motion for Summary Judgment of Class 7 Raw Material Supplier Claims (filed in Case No. 05-30551, Doc. No. 3)

¶ 36)

The Liaison Counsel notes that the component at issue is the silicone liquid/gel kit, which can be defective if it is designed defectively or fails to have adequate warnings. The Liaison Counsel argues that the gel kits were defective. The components contained a mixing kit to make silicone gel (Q7-2167 and 2168). The Liaison Counsel claims that Dow Corning knew that the silicone fluids were dangerous.

Based upon the submission of the parties, the Court finds there is a genuine issue of material fact as to whether the silicone gel kits provided by Dow Corning to Heyer-Schulte/Mentor were inherently defective or unreasonably dangerous. Dow Corning performed numerous tests where results appeared to show that the silicone fluids were defective or unreasonably dangerous, including the immunological effects its own scientists studied from the 1970s to the 1980s. (Condra Aff. I, Exs. 46, 49, 51, 53-55, 64-66, 69, 71-72, 92) There is also sufficient evidence to show a question of fact as to whether Heyer-Schulte/Mentor relied on Dow Corning's superior knowledge, as advertised by Dow Corning, regarding the safety of the silicone fluids. (Condra Aff. I, Exs. 34-35; Condra Aff. II, Ex. 3) Although Dow Corning submits the findings of the National Science Panel, the results of studies and reports issued by Dow Corning noted above and submitted by the Liaison Counsel create a question of fact as to whether the silicone fluids are defective or unreasonably dangerous.

As to Judge Pointer's findings regarding GE silicone, Judge Pointer noted that GE had done no testing to determine whether the substances were safe for use in implants. Judge Pointer further noted that GE did not promote its silicone materials as safe for use in implants and GE's product data sheets cautioned that the users were responsible for determining the safety, compatibility and

approval necessary for use in any medical application. 996 F.Supp. at 1115. In Dow Corning's case, Dow Corning advertised in its brochures its role as the pioneer and the leader in the industry. (Condra Aff. I, Exs. 11-12) Dow Corning performed numerous testing on liquid silicones that comprised up to 90% of the gel implant and finished gel itself but Dow Corning also observed adverse results, without notifying its customers as to any adverse results. (Condra Aff. I, Exs. 46, 49, 51, 53-55, 64-66, 69, 71-72, 92) Its brochures actively promoted that silicone gel was safe for implantation in the body. (Condra Aff. I, Ex. 11) Dow Corning further notified its customers that they did not need to further test the silicone gel because Dow Corning had already done the testing. (Condra Aff. I, Exs. 34-35) Judge Pointer found that GE did not possess knowledge of any danger in the product. *Id.* at 1114. Here, there is sufficient evidence to show that Dow Corning possessed knowledge that the product was dangerous or defective. Although the Litigation Facility argues that the GE gel and the Dow Corning gel were essentially identical, a closer reading of the submitted testimony shows that this statement was based on the molecular weight data and chemical tests which measures the angle that light is bent, not from testimony that specifically identified the chemical and molecular makeup of both the GE gel and the Dow Corning gel. (Ex. B to LF's Br. in 05-30551, ¶ 36)

There may be safe uses for the silicone gel or liquids but, with regards to implantation in the body, there is a genuine issue of material fact whether the product is inherently dangerous or defective based upon the submissions submitted by the parties.

3. Sophisticated Buyers

The Litigation Facility argues that there is no dispute that Heyer-Schulte/Mentor are sophisticated buyers as noted by Judge Pointer in his opinion. *Id.* at 1115. The Liaison Counsel

argues that Heyer-Schulte/Mentor, although competitors of Dow Corning in the breast implant product, relied on Dow Corning regarding the safety of the silicone fluids supplied by Dow Corning.

The Liaison Counsel submitted evidence to create a genuine issue of material fact that although Heyer-Schulte/Mentor may have been sophisticated buyers, they relied on Dow Corning's representations as to the safety of the silicone fluids supplied by Dow Corning. (Condra Aff. I, Exs. 34-35) The Liaison Counsel submitted evidence that from the 1960s through the 1980s, Dow Corning developed and tested various forms of silicone fluids. (Condra Aff. I, Exs. 46, 49, 51, 53-55, 64-66, 69, 71-72, 92) There is sufficient evidence submitted to create a genuine issue of material fact that Dow Corning informed Heyer-Schulte/Mentor not to perform further testing but to rely on Dow Corning's research on the safety of the silicone fluids.

4. Substantially Altered Materials

The Litigation Facility argues that Heyer-Schulte/Mentor substantially altered the materials so that Dow Corning was not liable for any injuries from the breast implants. The Liaison Counsel argues that Heyer-Schulte/Mentor simply took the gel kit received from Dow Corning and placed the silicone into their products.

Based on the evidence submitted by the Liaison Counsel, as to the silicone fluid/gel received from Dow Corning, there is a genuine issue of material fact that Heyer-Schulte/Mentor may not have substantially altered the silicone gel they injected into the products they manufactured, including the Becker Expander. There is sufficient evidence submitted that Heyer-Schulte/Mentor generally followed Dow Corning's mixing and cooking recommendations for the gel. (Condra Aff. I, Exs. 19, 21-24). Heyer-Schulte/Mentor may have manufactured their own breast implant shells and may have substantially altered the components and materials used for the breast implant shells. However,

as to the silicone gel injected into the breast implant shells, the Court finds there is a genuine issue of material fact that the silicone gel from Dow Corning was not substantially altered by Heyer-Schulte/Mentor.

5. Substantial Participation in Design

The Litigation Facility claims that Heyer-Schulte/Mentor designed and developed their own implants without Dow Corning's participation. The Liaison Counsel argues that while a claim that there is a manufacturing defect in a Heyer-Schulte/Mentor implant shell, there is also a defect in the gel supplied by Dow Corning and that Heyer-Schulte/Mentor relied on Dow Corning as to how the silicone gel was to be mixed. For the reasons set forth above, the Court finds there is a genuine issue of material fact that Dow Corning substantially participated in the manufacture of the silicone gel which may have been placed in the Heyer-Schulte/Mentor Becker Expander implant shells.

The Court finds that the Litigation Facility's Motion for Summary Judgment based upon the bulk supplier, raw material supplier, and/or sophisticated purchaser defense is denied as to the silicone fluid/gel used in the Heyer-Schulte/Mentor Becker Expander implant shells.

C. Rupture Claims

Dow Corning claims that the rupture claim alleged by Claimant in this Class 8 category should be dismissed. There is no dispute that Heyer-Schulte/Mentor developed their own outer shell properties. The Liaison Counsel argues that because Dow Corning had knowledge that the Heyer-Schulte/Mentor implant shells were susceptible to rupture, Dow Corning should be liable for any injuries caused by the leaked silicone gel. The Liaison Counsel claims that it was reasonably foreseeable that the Heyer-Schulte/Mentor implants, including the Becker Expander, would rupture.

In order to prevails in a manufacturing defect claim, a "plaintiff must show that the defect

existed at the time the product left the manufacturer." *Johnson v. Black & Decker (U.S.), Inc.*, 408 F. Supp. 2d 353, 357 (E.D. Mich. 2005). In a design defect case, the focus is on the manufacturer of the finished product. *Prentis v. Yale Manufacturing Co.*, 365 N.W.2d 176, 185 (Mich. 1984). The supplier of component materials or parts has no duty to analyze the design and assembly of the completed product of an unrelated manufacturer to determine if the component is made dangerous by the integration into the finished product. *Citizens Ins. Co. of America v. Sears Roebuck & Co.*, 203 F.Supp.2d 837, 847 (W.D. Mich. 2002).

The Court finds there is no genuine issue of material fact that Heyer-Schulte/Mentor manufactured the finished Becker Expander. Liaison Counsel has not submitted sufficient facts to create a genuine issue of material fact that Dow Corning participated in the manufacture and the design of the Becker Expander. Claimant has not sufficiently alleged a rupture claim against Dow Corning as to the Heyer-Schulte/Mentor Becker Expander. The rupture claim must be dismissed as to Dow Corning. However, any failure to warn claim that Claimant may allege in his Complaint as to the silicone fluid/gel remains as to Dow Corning.

III. CONCLUSION

For the reasons set forth above, the Litigation Facility's Motion for Summary Judgment is GRANTED IN PART and DENIED IN PART. Claimant is subject to the terms of the Amended Joint Plan of Reorganization, the Litigation Facility Agreement, and the various Case Management Orders entered in Case No. 00-00001 and any related cases. Accordingly,

IT IS ORDERED that the Litigation Facility's Motion for Summary Judgment Dismissing Class 8 Claim **(Doc. No. 3, filed 2/4/2008)** is GRANTED IN PART and DENIED IN PART as more fully set forth above.

IT IS FURTHER ORDERED that the Litigation Facility's Motion for Leave to File Reply Brief in Excess of Five Pages **(Doc. No. 13, filed 4/14/2008)** is GRANTED.

/s/ Denise Page Hood
DENISE PAGE HOOD
United States District Judge

DATED: March 30, 2009

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on this date, May 18, 2009, by electronic means and/or first class U.S. mail.

S/Sakne Srour
Deputy Clerk